



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 696,071	10 25 2000	James Norman Cawse	RD-28,030	3513

25101 7590 09 11 2003

PHILIP D FREEDMAN, PC
6000 WESTCOTT HILLS WAY
ALEXANDRIA, VA 22315

[REDACTED] EXAMINER

SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
1631	15

DATE MAILED: 09 11 2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/696,071	CAWSE ET AL.
	Examiner Carolyn L Smith	Art Unit 1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 11 July 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,7-14,18,19 and 21-25 is/are pending in the application.
 - 4a) Of the above claim(s) 21-25 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,7-14,18 and 19 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1,7-14,18,19 and 21-25 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>13</u> .	6) <input type="checkbox"/> Other: _____ .

DETAILED ACTION

Applicant's amendments and remarks in Paper No. 14, filed 7/11/03, are acknowledged.

Amended claim 1 and cancelled claims 3, 4, 6, 15, 16, and 17 are acknowledged.

Applicant's arguments, filed 7/11/03, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The IDS, filed 4/14/03 (and refiled 7/11/03), has been considered and signed by the Examiner.

Claims 1, 7-14, 18, and 19 are herein under examination.

Specification

The disclosure is objected to because of the following informalities: On page 2 of the specification, the Figures are not separately described in the section at the bottom of the page for several Figures. Appropriate correction is required.

Claims Rejected Under 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and

Art Unit: 1631

reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of the skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

LACK OF ENABLEMENT

Claims 1, 7-14, 18, and 19 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed invention.

It is not understood how the claimed invention is enabled for the calculation in independent claims 1 and 18. In part (A) a first experimental space is defined. In part (B) a second experimental space is defined by deleting duplicate factor combinations from the first experimental space. The second experimental space is therefore mathematically as follows:
Second experimental space = first experimental space minus duplicate factor combinations.

Therefore, a subtraction of duplicates is apparently performed to result in the second experimental space, but does not appear in the formula set forth in part (B) of claim 1 or claim 18.

On page 5 of the specification, the Ternary space calculation formula is derived in line 4 but also without any subtraction term for duplicates. Additionally, in the line just below the Table on page 5 of the specification, the number of experiments without overlap is calculated via the formula $Q_T \times E_T$. But, nowhere in the Ternary, Quaternary, etc. formulas below is there either the Q_T or the E_T formula shown that is set forth in Table 1 at the top of page 5, nor, of course, a subtraction of duplicate factor combinations. Therefore, this issue supports a lack of enablement rejection due to setting forth a formula in the independent claims which do not calculate what is described as the characteristics of the second experimental space as in the above formula.

Claims Rejected Under 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 7-14, 18, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claims 1 and 18 each recite a formula of the second experimental space as seen in part (B) of both claims which differs from the word explanation of a secondary experimental space (claim 1, lines 4-5 and claim 18, lines 4-6) which defined by deleting duplicate factor combinations from the first experimental space. The word interpretation of second experimental space is therefore mathematically as follows:

Second experimental space = first experimental space minus duplicate factor combination.

This subtraction of duplicates is apparently performed to result in the second experimental space, but does not appear in the formula set forth in part (B) of claims 1 and 18. Therefore, there appears to be an internal conflict as to what is meant by the metes and bounds of the second experimental space, the word explanation or the formula as set forth in part (B) of these claims. Clarification of the metes and bounds of these claims via clearer claim wording is requested. Claims 7-14 and 19 are also rejected due to their direct or indirect dependence from claims 1 and 18.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 8 A.M. to 4:30 P.M.

Art Unit: 1631

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.



September 8, 2003